UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: FLUOROQUINOLONE PRODUCTS LIABILITY LITIGATION

MDL No. 2642 (JRT)

THIS DOCUMENT RELATES TO:

Jennifer Akman v. Cobalt Laboratories, Inc. AKA Cobalt Laboratories LLC and *Actavis Pharma Co.*
Case No. 0:17-cv-00260-JRT.

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION FOR JUDGMENT ON THE PLEADINGS AND RECOMMENDING REMAND TO THE TRANSFEROR COURT

Master Docket Case No. 0:15-md-02642

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Plaintiff Jennifer Akman asserts claims under District of Columbia law against Defendants, manufacturers of generic ciprofloxacin ("Generic Defendants"), alleging they are liable for failing to provide her and her prescribing physician with a ciprofloxacin warning approved by the federal Food and Drug Administration ("FDA") in August 2013. The Court previously found that such state law claims are not always preempted, but granted Generic Defendants' first motion for judgment on the pleadings because Akman

did not state plausible, non-preempted claims. The Court gave Akman leave to amend, and she has now filed an amended complaint. Generic Defendants have filed another Motion for Judgment on the Pleadings, arguing that Akman has not identified a state law duty that gives rise to her claims independently from requirements under federal law, and therefore her claims are still not viable.

The Court will deny in part and grant in part Generic Defendants' Motion. Akman has stated negligence-based claims based on breach of the D.C. duty of reasonable or ordinary care—no greater or different duty is required to state non-preempted claims—and has stated a claim under the D.C. Consumer Protection Procedures Act, and thus the Court will deny the Motion with respect to Counts III, IV, and X. However, Akman's products liability claims are premised on federal law and therefore are not viable, and the Court will dismiss Counts I and II.

BACKGROUND

In November 2013, Plaintiff Jennifer Akman began taking the antibiotic ciprofloxacin. (1st Am. Compl. ¶ 7, Dec. 3, 2020, Docket No. 41.) Akman stopped taking the medication within 24 hours because of a severe adverse reaction, (*id.* ¶ 8), and within a few days of taking the medication, she went for a brief jog and could barely walk or stand afterward, (*id.* ¶ 9.) Akman continues to suffer nerve damage and other injuries, amounting to "Fluoroquinolone Associated Disability" or FQAD, (*id.* ¶ 10), and irreversible peripheral neuropathy, (*id.* ¶ 12.)

The FDA had approved an updated warning label for brand-name Cipro and generic-equivalent ciprofloxacin in August 2013 to describe the potential rapid onset and risk of irreversible peripheral neuropathy, and to eliminate the prior warning statement that neuropathy was a "rare" side effect. (*Id.* ¶¶ 19–21.) Akman alleges that the updated information was not included on the label or prescribing information for the generic version of the drug manufactured by Generic Defendants at the time she was prescribed the medication. (*Id.* ¶ 22, 25.) Generic Defendants' failure to update the drug label to include the FDA-required warning allegedly resulted in (1) Akman receiving ciprofloxacin instead of another non-fluoroquinolone antibiotic, (2) her healthcare providers failing to warn and instruct her about the risk of long-term injury, and (3) an absence of adequate warnings in patient information. (*Id.* ¶¶ 26–27.)

On November 14, 2016, Akman filed a Complaint against Cobalt Laboratories, Inc., also known as Cobalt Laboratories LLC ("Cobalt"), and Actavis Pharma Company, which has now been succeeded by amalgamation by Teva Canada Limited ("Teva"), in the Superior Court of the District of Columbia (the "Initial Complaint"). (Notice of Removal ¶¶ 1, 5–8, Jan. 17, 2017, Docket No. 1.) Defendants Cobalt and Teva (collectively, "Generic Defendants" or "Defendants"), are manufacturers of generic pharmaceutical products, including ciprofloxacin. (1st Am. Compl. ¶¶ 5–6.) Akman asserts claims for strict liability, product liability – failure to warn, negligence, negligent misrepresentation, and

unlawful and deceptive trade practice under D.C. Code § 28-3905, and asks for punitive damages. (*Id.* ¶¶ 28–81.)

Defendants removed the case to federal court in the District of the District of Columbia on January 17, 2017, and the case was then transferred to the fluoroquinolone multi-district litigation ("MDL") in the District of Minnesota. (*See* Docket No. 14.) On July 31, 2020, Generic Defendants filed a Motion for Judgment on the Pleadings pursuant to Federal Rule of Civil Procedure 12(c), arguing that Akman's claims based on the Generic Defendants' alleged failure to update their labels to match the FDA-approved label are preempted by federal law. (Mot. J. Pleadings, Jul. 31, 2020, Docket No. 29.)

On November 4, 2020, the Court granted the Generic Defendants' first motion for judgment on the pleadings. *See In re Fluoroquinolone Prods. Liab. Litig.*, No. 15-2642, 2020 WL 6489186 (D. Minn. Nov. 4, 2020). Nonetheless, the Court explained that failure-to-update claims are not per se preempted by federal law; rather, such claims may be viable if a plaintiff alleges that:

> (1) a generic drug manufacturer failed to update their labels to match an FDA-approved label adopted by brand-name manufacturers; (2) the claim is limited to the inadequacies of the non-updated label compared to the updated label; and (3) the claim is based on state law, such as common law negligence or a statutory duty, that would require generic manufacturers to update their labels irrespective of federal requirements.

Id. at *4. The Court found that Akman's Initial Complaint did not satisfy the requirements because her allegations were not limited to the inadequacies of the drug label from the failure to update, did not tie alleged liability to any specific requirements under D.C. law,

and the allegations were too interwoven with traditional failure to warn claims. *Id.* at *5. Yet because the Court found that there was a possible path around preemption and the Court had not previously analyzed the preemption question, the Court granted leave to amend. *Id.*

Akman filed an amended complaint on December 3, 2020, in response to which Generic Defendants filed answers on December 16, 2020. (Teva Ans., Dec. 16, 2020, Docket No. 43; Cobalt Labs. Ans. Dec. 16, 2020, Docket No. 44.) On December 30, 2020, Generic Defendants filed a second Motion for Judgment on the Pleadings, asserting that Akman's amended complaint still fails to state a claim based on the parameters set forth in the Court's November 4, 2020 Order. (2nd Mot. J. Pleadings, Dec. 30, 2020, Docket No. 46.)

DISCUSSION

I. STANDARD OF REVIEW

Judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) is "appropriate where no material issue of fact remains to be resolved and the movant is entitled to judgment as a matter of law." *Faibisch v. Univ. of Minn.*, 304 F.3d 797, 803 (8th Cir. 2002). When evaluating the merits of a motion for judgment on the pleadings, the district court applies the same standard that applies to a motion to dismiss. *See* Fed. R. Civ. P. 12(b)(6); *see also Ashley Cnty v. Pfizer*, *Inc.*, 552 F.3d 659, 665 (8th Cir. 2009). As such, to survive a motion for judgment on the pleadings, the complaint must contain

sufficient factual allegations to state a plausible claim for relief. *See Clemons v. Crawford*, 585 F.3d 1119, 1124 (8th Cir. 2009). A district court accepts as true all facts pleaded by the nonmoving party and draws all reasonable inferences from the pleadings in favor of that party. *Corwin v. City of Independence*, 829 F.3d 695, 699 (8th Cir. 2016). Merely reciting the elements of a cause of action is insufficient, and legal conclusions asserted in the complaint are not entitled to the presumption of truth. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). When deciding a motion for judgment on the pleadings, a district court refrains from considering matters beyond the pleadings, other than certain public records and "materials that do not contradict the complaint, or materials that are necessarily embraced by the pleadings." *Saterdalen v. Spencer*, 725 F.3d 838, 841 (8th Cir. 2013) (quotation omitted).

II. ANALYSIS

The Court must determine whether the amended complaint states a non-preempted claim against the Generic Defendants; in other words, whether the amended complaint satisfies the requirements stated in the Court's prior order. *See In re Fluoroquinolone MDL*, 2020 WL 6489186, at *4. The parties primarily dispute whether Akman has stated claims based on violations of state law, rather than merely claims derived from federal law. Generic Defendants argue that Akman has neither identified a D.C. statute that would require them to conform their labels to FDA requirements, nor identified a common law duty for them to do so; they assert that their only duty derives

from the federal "duty of sameness" under the federal Food, Drug, and Cosmetic Act ("FDCA"), and therefore Akman cannot state a claim. Akman maintains that her claims are based on D.C. law, both the common law duty of ordinary care and the statutory duty to not mislead consumers under the D.C. Consumer Protection Procedures Act ("CPPA").

Under D.C. law, the duty of a manufacturer or seller is one of ordinary care. *East Penn Mfg. Co. v. Pineda*, 578 A.2d 1113, 1118 (D.C. Ct. App. 1990). A manufacturer or supplier is liable for negligent failure-to-warn under D.C. law for "harm that results from foreseeable uses of [its] product if the supplier has reason to know that the product is dangerous and fails to exercise reasonable care to so inform the user." *Id.* (quoting *Payne v. Soft Sheen Prods. Inc.*, 486 A.2d 712, 721 (D.C. Ct. App. 1985). Contrary to Generic Defendants' understanding, this state law duty of ordinary care is a sufficient source of law for Akman to plead viable negligence claims. *See Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 586–87 (6th Cir. 2013) (explaining that state law tort principles provide an independent cause of action against generic drug manufacturers).

Rather than preempting Akman's state claims, the FDA-required warning label language plausibly provides the measure of that ordinary care; Akman may allege that a reasonable manufacturer would have included the most informative, strongest warning content available—irrespective of whether federal law required the manufacturer to do so. *Cf. id.* at 588 (finding that plaintiff could establish that defendants breached their duty

of reasonable care by failing to provide another available, more informative drug label without relying on the fact that failure to do so also constituted a violation of federal law).

Finding that D.C. law supports tort claims against the Generic Defendants, the Court next examines whether Akman has sufficiently pleaded each of her claims. Counts III and IV for negligence and negligent misrepresentation, respectively, satisfy the requirements to escape preemption because Akman's negligence claim alleges that the Generic Defendants had a duty to exercise reasonable care with respect to their product labels but breached that duty by failing to include the label contents approved by the FDA in August 2013 as a reasonable manufacturer would have. The negligent misrepresentation claim similarly alleges negligence, recklessness, and lack of due care—all of which give rise to liability under state law. Count X, pursuant to the D.C. CPPA likewise states a viable claim because Akman has plausibly alleged that the Generic Defendants' conduct violated D.C. law. That this same conduct also violates federal law is relevant only insofar as it means that complying with state law was not impossible—and thus impossibility preemption does not apply. As such, the Court will deny Generic Defendants' Motion as to Counts III, IV, and X because those claims are not preempted by federal law.[1]

[1] Although the Court finds that Akman has sufficiently pleaded her negligence-based and CPPA claims, the Court notes that it is far from certain whether Akman will ultimately be able to prove her claims. For example, Generic Defendants may be able to establish that they did act reasonably because the amount of time that passed between the August 2013 label update and when their product labels were changed to reflect the new content was reasonable. Or, as noted

However, the Court will grant Defendants' Motion with respect to Akman's products liability claims, Counts I and II. Unlike her other claims, Akman has not sufficiently connected these claims to D.C. law. For example, in Count II Akman has only alleged that the Generic Defendants "had a duty to provide warnings consistent with those required by the FDA." (Am. Compl. ¶ 39.) The source of Count I is thus the federal "duty of sameness," rather than the state duty of reasonable care, which Akman cannot enforce because there is no private cause of action under the FDCA. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). As such, the Court finds that Akman has failed to identify an independent, non-preempted state-law source for her products liability claims and the Court is not convinced that these claims are anything other than an attempt to enforce a federal law violation through state litigation.

III. REMAND TO TRANSFEROR COURT

In its Order granting the first motion for judgment on the pleadings and granting leave to amend, the Court asked the parties to submit briefing on whether this case should be transferred back to the District of the District of Columbia rather than remain in the Fluoroquinolone MDL, should Akman file a viable amended complaint. *See* 2020

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in the Court's November 4 Order, the learned intermediary doctrine could thwart Akman's claims. Additionally, the Court reiterates that, even if Akman proves negligence, any recovery will be limited to damages attributed solely to the differences in the label on the ciprofloxacin Akman received and relied on and the label approved by the FDA in August 2013.

WL 6489186, at *6. The parties submitted a joint memorandum on this issue, expressing agreement that the case should be transferred out of the MDL and back to the District of the District of Columbia. (Joint. Mem. at 2–3, Dec. 17, 2020, Docket No. 45.)

The Court agrees. Multidistrict litigation is intended to coordinate and consolidate pretrial proceedings for matters with common questions of fact, and cases must be remanded to their originating courts at the conclusion of pretrial proceedings, but the Court also has discretion to recommend remand during pretrial proceedings. 28 U.S.C. § 1407(a). The Judicial Panel on Multidistrict Litigation ("JPML") has the final say on remanding a case to the transferor court during pretrial proceedings, and bases its decisions on various factors, including whether everything remaining to be done in a proceeding is case-specific. *In re Bridgestone/Firestone, Inc.*, 128 F. Supp. 2d 1196, 1197 (S.D. Ind. 2001). Here, Akman's case presents unique issues and involves different defendants than the cases remaining in the MDL. Although courts may decline to suggest remand if doing so presents a risk of many similar requests taking over the MDL, *see In re Baycol Prods. Litig*., MDL No. 1431, 2007 WL 9717942, at *1 (D. Minn. Jul. 13, 2007), such circumstances are not present in this case since the MDL is nearing its conclusion. Therefore, the Court will recommend to the JPML that the case be remanded to the transferor court.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Defendants' Motion for Judgment on the Pleadings [Docket No. 46] is **DENIED in part and GRANTED in part**, as follows:
    a. Defendants' Motion is denied with respect to Counts III, IV, and X;
    b. Defendants' Motion is granted with respect to Counts I and II.
2. The Court recommends to the Judicial Panel on Multidistrict Litigation that this case is ready for remand to the transferor court, the United States District Court for the District of Columbia, because the action presents unique legal and factual issues and involves different defendants than the remaining cases in the *In re Fluoroquinolone Products Liability Litigation*, MDL No. 2642, and therefore will not benefit from additional pretrial consolidation.

DATED: July 20, 2021
at Minneapolis, Minnesota.

JOHN R. TUNHEIM
Chief Judge
United States District Court